510(k) Summary K073434

APR - 1 2008

Submitted by:
Keith Paluch
Director of Technical and Regulatory Affairs
Bipore Medical Devices, Inc.
31 Industrial Parkway
Northvale, NJ 07647

Date Prepared:
March 27, 2008

Proposed Device:
Bipore Accuflex™ Percutaneous Sheath Introducer

Product Classification:
Class II C.F.R. 870.1340 Product code: DYB, Catheter Introducer

FDA registration number:
2248069

Predicate Device:
K051513 Bipore Accuflex™ Percutaneous Sheath Introducer

Indications for Use:
The Bipore Accuflex™ Percutaneous Sheath Introducer is recommended for percutaneous introduction of various devices into arteries and/or veins for diagnostic and therapeutic procedures.

Device Description:
The Bipore Accuflex™ Percutaneous Sheath Introducer is a flexible tube designed for the percutaneous introduction of various devices into arteries and/or veins for a variety of diagnostic and therapeutic procedures. The product consists of a tube fabricated out of nylon based, flouropolymer lined material, reinforced by a flexible stainless steel wire within the tube. Proximally located on the flexible tube is an integral side port/hemostasis valve and/or female luer connection for attachment to a Touhy Borst adaptor. The side port, which provides a means of introducing contrast media or other fluids, is fabricated from non-DEHP PVC. The hemostasis valve is made from silicone rubber. The Touhy Borst adapter is a separate or connected component purchased from B.Braun. This purchased component is used in a manner consistent with B.Braun specification and premarket clearance. The proximal end contains a 24 karat gold radiopaque marker. The stainless steel coil enables the introducer to kink resistant during normal use. The proximal end may also contain a 45° to 180° radius bend. This pre-bend allows the product to be directed by transferring distal torque to steer the proximal tip. The reinforced tube, through which a vessel dilator or catheter is introduced is available in 5,6,7 and 8 French sizes and in lengths ranging from 5 cm to 110 cm.

Summary of Technical Characteristics as compared to the predicate device:

The proposed change modifies the exterior dimensions of hemostasis valve body by and adds additional size offerings to include lengths up to 110cm. The device may also contain an additional Polyethylene dilator for user convenience.

The proposed modification to the hemostasis valve improves the manufacturability of the device. This modification makes the device easier to handle by the user because of the reduction in bulk resulting by a change in length.

The slight increase in overall length to 110cm allows the device to be used with devices that require longer length sheaths.

The additional Polyethylene dilator improves the convenient use of the product when the user prefers a shorter or longer length dilator to accommodate patient anatomy.

Test results indicate that the modified product is in conformance with Bipore specifications and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Bipore, Inc.
c/o Mr. Keith Paluch
Director of Technical and Regulatory Affairs
31 Industrial Parkway
Northvale, NJ 07647

Re: K073434
Bipore Accuflex™ Percutaneous Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: March 17, 2008
Received: March 17, 2008

Dear Mr. Paluch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K073434

Device Name: Bipore Accuflex™ Percutaneous Sheath Introducer

Intended Use / Indication For Use: The Bipore Accuflex™ Percutaneous Sheath Introducer is recommended for percutaneous introduction of various devices into arteries and/or veins for diagnostic and therapeutic procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Vedsmed

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073434